UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

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| UNITED STATES OF AMERICA, | ) | |
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| Plaintiff, | ) | |
| | ) | |
| v. | ) | Case No. 4:14 CR 003 AGF |
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| OZKAN SEMIZOGLU and SABAHADDIN AKMAN, | ) | |
| | ) | |
| Defendants. | ) | |

**GOVERNMENT'S SENTENCING MEMORANDUM**

Pursuant to the Court's August 12, 2014 Order, the Government hereby files its sentencing memorandum and advises the Court that it will not present any testimony at sentencing of either defendant Semizoglu or Akman.

**I. The Nature, Circumstances, And Seriousness Of The Offense**

18 U.S.C. § 545 prohibits the knowing importation of any goods or merchandise "contrary to law." In this case, defendants pled guilty to smuggling prescription cancer treatment drugs from Turkey into the United States by using U.S. Customs declarations on the exterior of the packages that falsely identified the contents of each of their shipments as "gifts."

Each shipment was "contrary to law' in that the smuggled drugs were misbranded and adulterated in violation of U.S Food and Drug Administration ("FDA") laws regulating the labeling, storage, and shipment of prescription drugs. Defendants' drugs had dosage or use instructions in foreign languages, and sometimes had incorrect lot numbers, making them misbranded. Pre-sentence report ("PSR"), ¶ 19. Moreover, some of the cancer treatment prescription drugs defendant shipped to the United States needed to be kept at constant cold temperatures to maintain their potency and efficacy. PSR, ¶ 18. However, defendant's shipments failed to contain insulation or cold packs that would protect the drugs, making the drugs adulterated. PSR, ¶ 18. FDA drug violations are serious offenses:

> [Misbranding ] "... is not merely a "hyper-technical" violation of the [law]. It is, rather, a manifestation of a congressional plan to create a "closed system" designed to guarantee safe and effective drugs for consumers in the United States. Drugs that are not properly labeled for sale under federal law sometimes may be similar in substance to those that are sold legally within the United States. In other cases, however, they may be drugs with chemical compositions that are not yet approved by the FDA, drugs not manufactured in accordance with FDA rules, or drugs not transported or stored in a manner that is deemed safe by the FDA. ... [T]he labeling requirements cannot be segregated from other [legal] requirements in this way. Instead, they work in conjunction with the other statutory standards and FDA regulations to create a system that excludes noncompliant and potentially unsafe pharmaceuticals. This "closed system" ensures that approved prescription drugs are "subject to FDA oversight" and are "continuously under the custody of a U.S. manufacturer or authorized distributor," thus helping to ensure that the quality of drugs used by American consumers is consistent and predictable. *In re Canadian Import Antitrust Litigation*, 470 F.3d 785, 790-91 (8th Cir. 2006) (cites omitted).

Food and Drug laws "touch phases of the lives and health of people which, in the circumstances of modern industrialism, are largely beyond self-protection." *United States v. Dotterweich*, 320 U.S. 277, 280 (1943). In this case, the patients who received defendants' smuggled drugs had no practical ability to test the drugs they received, or determine their efficacy before infusion.

Some of the drugs smuggled to the United States by defendant were counterfeit, with non-genuine exterior packaging containing incorrect lot numbers. PSR, ¶ 19. Other packages smuggled by defendant were labeled as the cancer treatment drug Altuzan. In reality, the drug vials actually contained only mold and water, with no active drug ingredients. PSR, ¶ 20. Two cancer patients in the United States received counterfeit cancer drugs that defendants sold to others in related criminal cases, and these two patients experienced health problems during chemotherapy infusions of the counterfeit Altuzan drugs. PSR, ¶¶ 20.

It is unclear to the Government how deeply the defendants were involved with the creation of the counterfeit drugs and labeling. Defendants' status as Turkish nationals limited investigation by U.S. law enforcement of their day-to-day activities in Turkey. It is clear that defendants were aware generally of U.S. patients having problems with their Altuzan, but kept selling that drug. PSR, ¶ 20.

The legislative history to the Prescription Drug Marketing Act of 1987 ("PDMA") is instructive here. In the PDMA, now codified at 21 U.S.C. § 333(b)(1), among other issues, Congress limited the importation of prescription drugs after finding that "the integrity of the distribution system for prescription drugs is insufficient to prevent the introduction and eventual retail sale of substandard, ineffective, or even counterfeit drugs." Congress specifically noted the danger that imported drugs may become "subpotent or adulterated during foreign handling and shipment." House Report 100-76, 100th Congress, P.L. 100-293, April 30, 1987, Sec. 2, Findings (2), (4). Defendant's unprotected Turkey-to-Missouri shipments containing drugs that needed constant cold temperatures raised the issues of sub-potency and adulteration.

Congress was further concerned that drug importation was "a catalyst for a continuing series of frauds against American manufacturers and had provided the cover for the importation of foreign counterfeit drugs." Congress believed that "the effect of these several practices and conditions is to create an unacceptable risk that counterfeit, adulterated, misbranded, subpotent, or expired drugs will be sold to American consumers." House Report 100-76, Sec. 2, Findings (5), (8). In this case, defendant's smuggling business was lucrative, but it caused the risks that Congress perceived with unregulated drug importation. Defendants' business model of trying to source powerful cancer treatment drugs at the lowest price and ship them to the United States with the cheapest possible methods inevitably led to high risk drugs being infused into U.S.

patients. The only surprising fact on this record is that there are only two verified instances of patient harm, given defendants' customers in multiple states and the amount of drug sales.

## II. Restitution and Victim Notification

Looking at the smuggling charge in this case, the United States is the victim of the offense for the purposes of 18 U.S.C. § 3771(e), as it controls the Nation's borders, determines which shipments can enter and which shipments should be refused, and collects Customs duties.

Beyond defendants' lack of easy-to-locate assets, calculating restitution would be difficult and would unduly prolong the sentencing process, as figuring out the Customs duties owed to the United States on multiple smuggled drug shipments over several years would be difficult and imprecise. Given the deceptive Customs declarations, the Government does not know exactly how many smuggled shipments were made, or what was in each package. As such, Akman's plea agreement seeks a fine and a forfeiture, but not restitution. In any event, fines, forfeitures, or a restitution order for unpaid Customs duties all benefit the United States.

Beyond consulting with the FDA and U.S. Customs, the Government has notified the families of the two cancer patients who received Altuzan from defendants of the plea agreement, the date of sentencing, and other issues related to the case and investigation. Members of the families have written letters to the Court expressing their thoughts, which are filed as Exhibit 1 to this motion. Identifiers (e.g. home addresses) in the letters have been redacted in the Court filing, and an unredacted copy of the letters will be filed under seal. Members of the families may also attend sentencing.

In terms of identifying other patients that may have been harmed by defendant's conduct, defendants shipped a large amount of drugs to various wholesale customers in the United States. However, the United States does not have complete records on which doctors ultimately ended up with the drugs, or which of each doctor's patients received the illegal drugs. Even when the United States has information regarding a doctor who purchased drugs from defendant and related individuals, it is still hard to determine which patients actually received the suspect drugs. Often, U.S. doctors in this investigation purchased FDA-approved drugs from a legitimate U.S. based wholesaler during some time frames when they were also purchasing drugs from illegal foreign wholesalers. Their medical records typically did not identify the source of any medicine that each patient received. Absent the unusual and immediate reactions of the two cancer patients in Arizona, the United States is not in a position to identify other patients who were harmed by defendants' drugs.

Roche is the drug manufacturer of the three substances identified in each of the smuggling counts in the Indictment. The United States has worked cooperatively with Roche throughout the investigation, and provided the company with the ability to attend Court events or write a letter for the Court. To date, the company has not provided a letter.

**III. Relief Requested.**

The Government respectfully requests that the Court sentence defendants in accordance with the plea agreements of defendants, and grant such other and further relief as the Court deems just and proper.

Respectfully submitted,

RICHARD G. CALLAHAN
United States Attorney

/s/ Andrew J. Lay
Andrew J. Lay
Assistant United States Attorney
111 South 10th Street, Room 20.333
St. Louis, Missouri 63102
(314) 539-2200

**CERTIFICATE OF SERVICE**

I hereby certify that on October 16, 2014, the foregoing was filed electronically with the Clerk of the Court to be served by operation of the Court's electronic filing system upon the following:

Clinton Wright and David Bruns, counsel for defendants

/s/ AUSA Andrew J. Lay